Section 5. 510(k) Summary

JUN 2 1 2011

K110946

510(k) SUMMARY TEMPLATE

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter: Galil Medical Ltd.
Tavor 1 Building
Shaar Yokneam
Yokneam Industrial Park 20692
Israel

Company Contact Person: Ms. Lynne Davies
Sr. Regulatory Affairs Advisor
Galil Medical Inc.
Phone: 651-287-5098
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Device Name: IceRod *Plus* 17G Cryoablation Needles

Device Classification Name: Cryosurgical unit and accessories (GEH)
21 CFR 878.4350

Predicate Device: IceRod 17G Cryoablation Needle (K051052)
IceRod 17G 90° Cryoablation Needle (K060144)

Device Description:
The IceRod *Plus* 17G Cryoablation Needles are sterile, single use, disposable components used in conjunction with a Galil Medical Cryoablation System when performing cryoablative destruction of tissue. They are intended to convert high-pressure gas to either a very cold freezing application or to a warm thawing application. The IceRod *Plus* needles are available in two configurations, straight and angled 90°. Each 17-gauge (17G) disposable cryoablation needle has a sharp cutting tip, a shaft, a color-coded handle, a gas tube, and a connector. Additionally, each needle exhibits markings every 5 mm to aid in positioning the needle in tissue. The IceRod *Plus* needles differ from the predicate device in that they contain an inner vacuum insulated tube to provide additional shaft insulation during a cryoablation procedure.

Intended Use:
Galil Medical Cryoablation Systems are intended for cryoablative destruction of tissue during surgical procedures. The cryoablation systems is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is

designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

Galil Medical Cryoablation Systems have the following specific indications:

• **Urology**	Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH)
• **Oncology**	Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention
• **Dermatology**	Ablation or freezing of skin cancers and other cutaneous disorders Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin
• **Gynecology**	Ablation of malignant neoplasia or benign dysplasia of the female genitalia
• **General surgery**	Palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas
• **ENT**	Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth
• **Thoracic surgery**	Ablation of arrhythmic cardiac tissue cancerous lesions
• **Proctology**	Ablation of benign or malignant growths of the anus or rectum, and hemorrhoids

Summary of Performance Data and Substantial Equivalence:
The IceRod *Plus* Cryoablation Needles have the same intended use and method of operation as compared to the predicate devices. The IceRod *Plus* needles differ in design in that they contain an inner vacuum insulated tube to enhance shaft insulation during the cryoablation procedure. Both the new and predicate devices consist of a sharp cutting tip, a shaft, a color-coded handle, a gas tube, and a connector. Both the new and predicate devices are comprised of similar materials and serve as conduits for high pressure gas during a cryoablation procedure.

Performance testing was conducted on the IceRod *Plus* Cryoablation Needles to verify safety and performance characteristics and to establish substantial equivalence. Testing was conducted according to protocols based on international standards and in-house requirements and included dimensional testing, functional testing, freezing performance

and stability. Additionally, the needles meet the biocompatibility requirements outlined in ISO 10993. Test results demonstrated that the IceRod *Plus* needles meet defined specifications and do not raise any new safety or effectiveness issues.

Conclusion:
The information and data provided in this 510(k) Notification establish that the IceRod *Plus* 17G Cryoablation Needles are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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% Ms. Lynne Davies
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Tavor 1 Building, Shaar Yokneam
Yokneam Industrial Park 20692
Israel

JUN 2 1 2011

Re: K110946
Trade/Device Name: IceRod™ Plus Cryoablation Needles
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 21, 2011
Received: May 25, 2011

Dear Ms. Davies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110946

Device Name: IceRod™ *Plus* Cryoablation Needles

Indications For Use:
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Galil Medical Cryoablation Systems have the following specific indications:

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- Dermatology (ablation or freezing of skin cancers and other cutaneous disorders. Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas small hemanglomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemanglomas, perianal condylomata, and palliation of tumors of the skin.)
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- General surgery (palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenoma)
- ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth)
- Thoracic surgery (ablation of arrhythmic cardiac tissue cancerous lesions)
- Proctology (ablation of benign or malignant growths of the anus or rectum, and hemorrhoids)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R. Dyke for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110946